

Final

HIPAA PRE-EMPTION ANALYSIS REPORT

Prepared for:

**Arizona Health Care Cost
Containment System
(AHCCCS)**

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HIPAA PRE-EMPTION ANALYSIS REPORT

EXECUTIVE SUMMARY

This Report addresses the need to compare existing federal and state regulations relating to the privacy of confidential health information with the standards mandated in the Health Information Portability and Accountability Act Privacy Rule, 45 CFR Parts 160 and 164, Subpart E (December 28, 2000, modified August 14, 2002). As discussed and agreed upon between FourThought Group and the AHCCCS Privacy- Security Project Sponsor, this document consists of a high-level summary, matrix and analysis. Given the complexity of the HIPAA Privacy Rule and the myriad of federal and state laws, a more detailed analysis of federal and state law interactions must be evaluated as individual circumstances arise. FourThought Group has worked closely with the AHCCCS Office of Legal Assistance to cross-walk those state laws most directly applicable to the Medicaid Program, as well as the federal Medicaid Law (CFR 42, Part 431 Subpart 431 (and its state counterpart AAC R 9-22-512) and the federal Substance Abuse Law (CFR 42, Part 2).

The basis of Preemption stems from the Supremacy Clause of the United States Constitution, where federal law supercedes state laws when the two conflict. The Privacy Rule Part § **160.203 General rule and exceptions**, specifies that

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law.

There are exceptions to this rule that are delineated and discussed under Section 3 of this report, including a key provision allowing that a state law standard may preempt a standard of the HIPAA Privacy Law if it affords more privacy protections to the patient and/or greater access to his/her records. Section 3 also summarizes the findings of the Arizona Hospital and Healthcare Association (AZHHA) Pre-emption Report, several state laws, and findings where there are more stringent state law standards than those in HIPAA Privacy. In addition, Section 3.2 includes an extensive preemption matrix, cross-walking and comparing the HIPAA standards to comparable standards of selected state and federal laws.

Significant findings regarding more stringent provisions of state law generally involve disclosure of member information without consent or authorization and include:

- ❑ Medicaid Statute – Arizona Administrative Code (AAC) R9-22-512 thru 31¹

¹ A.A.C. R9-22-512 establishes the requirements for safeguarding applicant and recipient information for the AHCCCS Title XIX acute care programs. Similar provisions or cross references are included in the Administrative Code for the Health Care Group Program (R9-27-507), the Long Term Care Program (R9-28-514), the Premium Sharing Program (R9-30-512), and the State Health Insurance for Children Program, known as "KidsCare" (R9-31-512). For simplicity's sake, references in this document to R9-22-512 or to the "AHCCCS rule" apply equally to all of these programs.

- Disclosures only as related to the administration of the Medicaid program, has particular relevance for the permitted disclosures such as law enforcement under HIPAA 164.512
- Mental Health
 - Needs to be analyzed per provision of the Mental Health Law, as both HIPAA and state law are consistent in some circumstances and more or less stringent in others. For example, the HIPAA rules governing psychotherapy notes are more stringent than state statute. Regarding mental health records, the AZHHA report recommends careful scrutiny on a case-by-case basis, with legal consultation.
- HIV/AIDS
 - State statute is very specific regarding disclosure of test results and other information without patient authorization and will be more stringent than HIPAA in some provisions
- Genetic Testing
 - State statute is very specific regarding disclosure of test results and other information without patient authorization and will be more stringent than HIPAA in some provisions
- Minors
 - State laws prevail

With regard to federal laws, the Preamble to the Final Privacy Rule, December 2000, discusses the need for a review and interpretation of the interaction of other federal laws with HIPAA Privacy. Strictly speaking, this is not a “pre-emption” issue as it does not involve the supremacy of federal law over conflicting state law. Nevertheless, the Secretary does acknowledge potential confusion over the interaction between separate federal regulatory schemes. DHHS recognizes the need for covered entities to review and understand this interaction, but also maintains that there should be few conflicts. This is further discussed in Section 4, with analysis and references to the matrix presented in Section 3.2. AHCCCS and FourThought Group agreed to focus its specific comparisons on the Medicaid law and on the substance abuse confidentiality law. Appendix B consists of a summary of other selected federal laws as excerpted from the HIPAA Privacy Regulations (December 2000) Preamble.

Significant findings regarding more stringent provisions of federal law generally involve disclosure of member information without consent or authorization and include:

- Federal Alcohol and Other Drug Confidentiality Law applies to licensed substance abuse treatment providers and excludes some disclosures without patient authorization or consent that are permitted by HIPAA Privacy.
- Title XIX/Medicaid specifically excludes disclosures without authorization unless such disclosure is related to the administration of the program.
 - HIPAA permits disclosures without authorization to law enforcement

under certain circumstances; however Medicaid does not.

Section 5 of this report briefly discusses the next steps, with an ongoing need to review state federal laws and statutes in relation to the HIPAA Privacy Regulations. The impact of preemption on the development and revision of AHCCCS policies and procedures to ensure compliance by April 14, 2003 is also discussed.

1.0 INTRODUCTION

This section provides more detail on the preemption provisions of the Privacy Regulations, delineates the objectives of this preemption analysis and discusses the scope of the laws covered as agreed upon between FourThought Group and AHCCCS.

As stipulated in **§160.203**, the general rule that federal law supercedes state law applies, except under one or more several conditions, including:

- ❑ The State appeals to DHHS and a determination is made by the Secretary that the state law is necessary to prevent fraud and abuse, ensure state regulation and reporting, and/or serves a compelling need related to health, safety and welfare.
- ❑ The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification of HIPAA Privacy
- ❑ The provision of State law, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.
- ❑ The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals

Several definitions relating to preemption are included in **§ 160.202 Definitions**.

- ❑ *Contrary*, when used to compare a provision of State law to a federal privacy standard, requirement, or implementation specification means:
 - (1) A covered entity would find it impossible to comply with both the State and federal requirements; or
 - (2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives HIPAA
- ❑ *More stringent* means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification a State law that meets one or more of the following criteria:
 - (1) The law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under HIPAA, except if the disclosure is required by DHHS in connection with determining whether a covered entity is in compliance with HIPAA or if the disclosure is to the individual who is the subject of the information.
 - (2) Permits greater rights of access or amendment to the individual, who is the subject of the individually identifiable health information,
 - (3) Provides a greater amount of information to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies,
 - (4) Provides requirements that narrow the scope or duration, increases the privacy protections afforded, or reduces the coercive effect of the circumstances surrounding the legal permission from an individual,

- (5) Provides for the retention or reporting of more detailed information or for a longer duration of record keeping for an accounting of disclosures,
 - (6) Provides greater privacy protection for the individual who is the subject of the individually identifiable health information.
- ❑ *Relates to the privacy of individually identifiable health information* means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information.
 - ❑ *State law* means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law.

1.1 Objectives

The objectives of this Preemption Analysis are

- ❑ To compare selected state and federal laws with requirements of the HIPAA Privacy Rule, with particular emphasis on those standards which are more stringent than comparable HIPAA standards.
- ❑ To summarize and analyze the Arizona Hospital and Healthcare Association report, *HIPAA Preemption and Arizona Law: Application and Analysis*.
- ❑ To describe those state and selected federal requirements that are more stringent than comparable HIPAA Privacy requirements as they affect AHCCCS policy development and compliance with the HIPAA Privacy standards.

1.2 Scope

This report includes research from several sources (see Appendix A, References) and crosswalks of standards, comparison, and analysis of the following selected State and Federal laws. There is narrative in Sections 3 and 4 and a Matrix in Section 3.2.

- ❑ AAC R 9-22-512 and related AHCCCS rule provisions
- ❑ ARS 12-2291 thru 2297
- ❑ ARS 12 2281-2287
- ❑ ARS 12- 2801-2804
- ❑ ARS 36 507, 509, 661, 663
- ❑ ARS 36-2903, 2917, 2918, 2992
- ❑ ARS 13-1413
- ❑ ARS 25-403
- ❑ ARS 44-132-133.01
- ❑ 180 F.3rd 1022 case law
- ❑ CFR 42 Title XIX
- ❑ CFR 42, Part 2, Confidentiality of Alcohol and Other Drugs

Regarding state law analysis, the above state laws were selected by AHCCCS Office of Legal Assistance (OLA) from the AZHHA Report as specifically affecting the Medicaid program. For purpose of analysis of federal laws, AHCCCS and FourThought Group agreed to focus its specific comparisons on the Medicaid law and on the substance abuse confidentiality law. Appendix B consists of a summary of other selected federal laws as excerpted from the HIPAA Privacy Regulations (December 2000) Preamble.

2.0 METHODOLOGY

FourThought Group discussed the formatting and methodology to create this report with the AHCCCS OLA Project Sponsor. Several meetings were conducted and drafts of both the outline and the Matrix were exchanged and finalized. The following activities occurred in order to produce this report:

- ❑ Maintain ongoing communication between FourThought Group and AHCCCS OLA regarding this report
- ❑ List HIPAA Privacy requirements and update Internet hyperlinks on Matrix to reflect the final modifications to the Privacy Regulations
- ❑ Conduct research on the Internet and review documents, including AZHHA copyrighted report
 - Arizona laws and administrative code on legal websites
 - Health Privacy Project
 - AZHHA report
 - Federal substance abuse law and websites
 - HIPAAgives and other state websites
 - WEDI-SNIP website and papers on preemption
 - HIPAA December 2000 Preamble
 - HIPAA Privacy Regulations Final Modifications, August 2002
- ❑ Develop Matrix format
- ❑ Conduct review and analysis of laws
 - Validate and update the AZHHA report to reflect final modifications, applicability, and legal interpretations of the analysis conducted by their legal contractor.
 - Review and analyze provisions of the Arizona Administrative Code (AAC) pertaining to AHCCCS, R 9 22-512
 - Analyze provisions of federal substance abuse law, CFR 42, Part 2
- ❑ Crosswalk provisions of each selected law with the HIPAA Privacy requirements and enter onto Matrix
- ❑ Analyze differences between the requirements and enter onto form when one of the laws is more stringent than HIPAA and/or if further comment is needed
- ❑ Create narrative and report

3.0 PREEMPTION OF STATE LAW

In general, the state of Arizona has many statutes protecting the privacy and confidentiality of medical and behavioral health records. Arizona statutorily grants patients the right of access to their medical records in the possession of health care providers (including physicians, hospitals, pharmacists and others) and insurance entities. The state also restricts the disclosures of confidential medical information made by these entities. Additional privacy protections are addressed in statutes governing other specific entities or medical conditions.

The Health Privacy Project of the Institute For Health Care Research and Policy at Georgetown University, in its 2002 Arizona update, *The State of Health Privacy*, reviewed state laws and statutes regarding privacy and confidentiality of patients and medical records, and categorized them by Provider and Insurance Entities under the subject headings of

- ❑ Patient Access
- ❑ Restrictions on Disclosure
- ❑ Privileges
- ❑ Condition Specific Requirements
 - Cancer, birth defects and other chronic diseases
 - Communicable Diseases, including HIV
 - HIV
 - Genetic Testing Information
 - Mental Health

The Health Privacy Project merely summarized the laws in the above categories; it did not perform a preemption analysis. The summary also was incomplete, as it did not address the dominant statute governing the Medicaid program, Arizona Administrative Code R9-22-512, or other statutes governing the AHCCCS program and its contractors. For purposes of the Medicaid program, AHCCCS and any of its health plan and other contractors are not subject to the Arizona Insurance Information and Privacy Protection Act A.R.S. § 20-2101), but are subject to Arizona Administrative Code (AAC) R9-22-512, which mirrors, in part, the federal Medicaid XIX Law. The sections below include a brief description of other pertinent Arizona laws affecting AHCCCS and its contractors and providers as well as a crosswalk and analysis where state laws may be more stringent.

3.1 Review and Update Of AZHHA Report

In 2001, the Arizona Hospital and Healthcare Association (AZHHA) contracted with the law firm of Coopersmith Gordon Schermer Owens & Nelson PLC to produce a copyrighted report, HIPAA Preemption and Arizona Law: Application and Analysis. The report has not been updated to include revisions and additions made in the Modifications to the Privacy Regulations, August 2002, and such an update is not scheduled to occur until early 2003. For the purposes of the AHCCCS and FourThought Group review and analysis, the most critical update is

the repeal of the requirement to obtain consent to use and disclose patient information. Some of the state law provisions that AZHHA deemed to be compatible with HIPAA consent provisions may now appear to be more stringent, and will apply or preempt HIPAA. Such an application of the law may require AHCCCS, providers and health plans to obtain an authorization from individuals to release their health information, even if for treatment, payment or operations.

As with the Health Privacy Project, the AZHHA report did not review or compare applicable sections of Arizona Administrative Code (AAC), R 9-22-512 or the related AHCCCS rules, which governs AHCCCS and its contractors. The matrix in Section 3.2 does include a crosswalk and analysis for that law. Those rules include provisions for confidentiality, use and disclosure of member records, and policy and procedures for the AHCCS programs:

- ❑ Chapter 22, Arizona Health Care Cost Containment System (AHCCCS) – Establishes the rules applicable to the Title XIX acute care populations including:
 - ❑ AHCCCS Medical Coverage for Families and Individuals
 - ❑ AHCCCS Medical Coverage for People who are Aged, Blind, or Disabled
 - ❑ Breast and Cervical Cancer Treatment Program
 - ❑ Qualified Medicare Beneficiary (QMB) (A.A.C. Title 9, Chapter 29)
- ❑ Chapter 27, Health Care for Private Employer Groups
- ❑ Chapter 28, Arizona Health Care Cost Containment System (AHCCCS) – Arizona Long-term Care System (ALTCS)
- ❑ Chapter 30, Arizona Health Care Cost Containment System (AHCCCS) – Premium Sharing Program
- ❑ Chapter 31, Arizona Health Care Cost Containment System (AHCCCS) – Children’s Health Insurance Program (Title XXI).

The following is a brief summary of other laws affecting AHCCCS and its contractors, with a description of the compatibility with HIPAA. Specific sections of each of these laws cross-walked with HIPAA standards are delineated in the Matrix in Section 3.2. Those standards that may be more stringent are noted in the matrix, as well.

- ❑ Arizona Revised Statutes (ARS) 12-2291 thru 2293 addresses patient rights and access to their medical records, including a definition of health care decision maker akin to the HIPAA definition of personal representative and definitions of medical records. These sections also include authorization requirements and exceptions, specifying that records cannot be disclosed without patient authorization and that a third party payor must separately obtain a patient’s written authorization to receive the information. However the exception standard allows such disclosures **as required by other laws (e.g. AAC R9-22-512; HIPAA)**. Most of the other provisions are consistent with comparable HIPAA standards.

- ❑ ARS 12-2294 thru 2297 address disclosures to third parties, such as legal services, ambulances, payers, legal representatives of deceased persons, and attending physicians. This section also stipulates as to charges for copies of medical records to patients and requirements for record retention. These provisions are predominantly consistent with the HIPAA standards.
- ❑ ARS 12-2281 thru 2287 addresses compliance with subpoena of health care records, including notice to patients, issuances, exceptions, affidavits and copies. The provisions are not contrary to HIPAA and the State law service requirements still apply. HIPAA is more stringent regarding the litigation disclosure requirements in the privacy notice, and will preempt the state standard.
- ❑ ARS 12-2801 thru 2804 requires confidentiality of genetic testing individually identifiable information, with written, informed consent. It is more protective of patient rights than the HIPAA standards and limits the types of entities that can receive the protected information even with a consent or authorization. ARS 12-2802(A) includes only these persons with consent:
 - The person tested
 - Any person or personal representative authorized in writing by the person tested
 - A researcher for medical or public health purposes **only** if the research is conducted pursuant to state and federal research laws or if the identity of the person is de-identified
 - A third person if approved by a human subjects review committee or a human ethics committee, with respect to persons who are subject to an Arizona cancer registry.
 - An employee of a health care provider if all of the following are true:
 - The health care provider performs the test or is authorized to obtain the test results by the person tested for the purposes of genetic counseling or treatment.
 - The employee provides patient care, treatment or counseling.
 - The employee needs to know the information in order to conduct the test or provide patient care, treatment or counseling.
 - A health care provider that procures, processes, distributes or uses a human body part from a deceased person with respect to medical information regarding that person or for the purpose of artificial insemination
 - A health care provider to conduct utilization review, peer review and quality assurance pursuant to other state law

- The authorized agent of a federal, state or county health department to conduct activities pursuant to the other state laws for the birth defects registry, children's rehabilitative services, newborn screening and sickle cell diagnosis and treatment programs and chronic, environmentally-provoked and infectious disease programs.
- To obtain legal advice, the legal representative of a health care provider that is in possession of the medical record.
- A health care provider that assumes the responsibility to provide care for, or consultation to, the patient from another health care provider that had access to the patient's genetic records.

Furthermore, under this law, the above persons cannot disclose the test results to another person or entity. If genetic testing information is subpoenaed, a health care provider shall respond pursuant to section 12-2282 (see above reference). So these provisions are more stringent and would preempt comparable permitted disclosure standards under HIPAA. Other provisions within these statutes are less restrictive, and HIPAA would apply.

- ARS 13-413 allows minors to consent to examination and care in connection with a sexual assault, should the parents or guardians be unavailable. **General Note on Minors:** Under current Arizona law, in those instances where a minor can consent to treatment, the minor may access his or hers own records without parental consent, and the parents may not obtain a copy of the minor's records without the minor's consent. Under HIPAA, state laws apply governing minors and their medical records.
- ARS 25-403 H. also addresses minors and provides that, unless otherwise provided by court order or law, both parents, even non-custodial parents, are entitled to have equal access to documents and other information concerning the child's education and physical, mental, moral and emotional health including medical, school, police, court and other records directly from the custodian of the records or from the other parent.
- ARS 44-132, 132.01 133 and 133.01 also address the rights of minors to consent to treatment and access their records and for venereal disease, emergency services and drug treatment respectively. Emancipated minors have full rights to access their records, consent to treatment and deny access to their parents. Under current Arizona law, minors may not have access to their records unless emancipated or if they fall under one of the laws mentioned in Titles 13, 25 (above), 44 or 36 below. Again, it should be noted that state law prevails on the question of minors under HIPAA.

- ❑ ARS 36 – 661(2), 663 address the capacity of the minor to consent to HIV testing. If the physician determines the minor is mature enough to make that decision, the parent’s consent will not be necessary.
- ❑ 180.F.3rd 1022 (9th Circuit Court, 1999) is case law (Planned Parenthood v Lawall) allowing the rights of minors to consent to abortion, contraception, and prenatal care. This means that minors, in such cases would have rights to access their records and refuse access to their parents without authorization.
- ❑ ARS 36 – 507 refers to mental health treatment and provides that records may not be released to the patient if the provider determines it is not in the best interests of the patient and such denial is necessary to protect the safety of the patient or others. This is consistent with HIPAA exceptions to patient access.
- ❑ ARS 36 - 509 also refers to mental health treatment and governs the confidentiality of mental health records. Under this law, all information obtained in the course of court ordered services are given special protection and may only be disclosed in certain circumstances. These provisions are more stringent than the HIPAA final modifications and will apply, meaning that authorizations will be needed to use or disclose such information, regardless of whether it is for treatment, payment or health care operations. All other mental health records are not subject to any special protections, and the HIPAA regulations with reference to psychotherapy notes will apply and preempt state law. The removal of consent from the final modifications makes the HIPAA standards (other than for psychotherapy notes) predominantly consistent with state law, with some other exceptions noted on the matrix in Section 3.2. Regarding mental health records, the AZHHA report recommends careful scrutiny on a case-by-case basis, with legal consultation.
- ❑ ARS 36-664 thru 665 addresses the confidentiality of communicable disease information with some special protections. Information may not be re-disclosed except in limited circumstances. State law on disclosures for treatment, payment and operations are generally more stringent and will still apply. Disclosures for other purposes often will require patient authorization under HIPAA and the authorizations/releases under HIPAA are more stringent than state law and must conform to HIPAA Privacy regulations.

ARS 36- Chapter 29 relates to AHCCCS specifically, with applicable sections:

- ❑ ARS 36-2903(I) permits the Director (subject to other state laws) to establish by rule the types of information that are confidential and circumstances under which such information may be used or released, including requirements for physician-patient confidentiality. Notwithstanding any other provision of law, such rules shall be designed to provide for the exchange of necessary information among the counties, the administration and the department of economic security for the purposes of eligibility determination under this article. It also allows a member's medical record to be released without the member's consent in suspected cases of fraud or abuse to an officer of AHCCCS's fraud control unit who has submitted a written request for the medical record.
- ❑ ARS 36-2918; 2992 govern AHCCCS fraud and abuse investigations, requiring providers to disclose information to AHCCCS when conducting such investigations. These disclosure requirements still apply as the Privacy standards allow for disclosures *as required by other law* (164.512 (a))

3.2 Preemption Matrix

The matrix format on the following pages was adapted from several versions in use around the country, with special appreciation to the North Carolina Healthcare Information and Communications Alliance (NCHICA), a leader in state HIPAA compliance activities, and HIPAAGives, a collaboration and website of state HIPAA activities. AHCCCS OLA and FourThought Group jointly finalized the template format. Applicable provisions of the state laws referenced above, as well as two federal laws are cross-walked with standards from the HIPAA Privacy Regulations, final modifications, August 2002. Each standard is hyperlinked to a website containing the full text from the regulation. The status column is used when the state or federal law is more stringent than HIPAA and would take precedence. Otherwise, it may be inferred that the provisions are consistent or HIPAA preempts state law. An analysis column on the far right of the matrix may contain additional information or can be used in the future for additional legal opinions.

4.0 Subpart E – Privacy of Individually Identifiable Health Information Matrix

Note: This matrix contains only rules with a state or federal reference. For an expanded version of this matrix showing all rules see the supplementary spreadsheet accompanying this document.

Rule #	Description	State Law Reference/Description	Status	Title XIX Medicaid Reference/Description	Status	Federal Substance Abuse Confidentiality Reference/Description*	Status	Analysis
164.5	Applicability.							
	http://www.bricker.com/attser/v/practice/hcare/hipaa/164.500.asp					Hospitals and outpatient facilities that receive any federal support, 42 USC 290dd-1(a) Qualified service organization, defined 42 CFR 11. Disclosures permitted. 42 CFR 2.12(c)(4).	HIPAA has broader applicability	
164.501	Definitions.							

<u>Rule #</u>	<u>Description</u>	<u>State Law Reference/ Description</u>	<u>Status</u>	<u>Title XIX Medicaid Reference/ Description</u>	<u>Status</u>	<u>Federal Substance Abuse Confidentiality Reference/ Description*</u>	<u>Status</u>	<u>Analysis</u>
	Individually identifiable health information defined, §164.501.					Identity, diagnosis, prognosis, or treatment relating to substance abuse education, prevention, training, treatment, rehab, or research by any federal dept. or agency. 42 USC 290dd-2(a); 42 CFR 2.11	Parts of definitions are consistent with HIPAA, but "persons who have applied for services" is more inclusive of a protection.	
						Includes persons who have applied for services as well.		
164.502	Uses and disclosures of protected health information: general rules.							

Rule #	Description	State Law Reference/ Description	Status	Title XIX Medicaid Reference/ Description	Status	Federal Substance Abuse Confidentiality Reference/ Description*	Status	Analysis
	(a) Use and disclosure for treatment, payment and health care operations	12-2292(A) R9-22-512		42 CFR 431.301		If state law conflicts, stricter prohibitions apply, 42 CFR 2.20 §290dd-2(a); 42 CFR 2.14, 2.13(a), 2.22; criminal justice - To persons who set participation as a condition of a criminal proceeding, 42 CFR 2.35. ;	Some provisions are more stringent as noted in following sections	R9-22-512 limits use and disclosure of information concerning AHCCCS applicants and recipients to purposes directly related to the administration of the program. 42 CFR 431.301 is the federal basis for this state rule.
	(b) Minimum necessary					Minimum necessary, 42 CFR 2.13(a).		

<u>Rule #</u>	<u>Description</u>	<u>State Law Reference/Description</u>	<u>Status</u>	<u>Title XIX Medicaid Reference/Description</u>	<u>Status</u>	<u>Federal Substance Abuse Confidentiality Reference/Description*</u>	<u>Status</u>	<u>Analysis</u>
	(d) Creation of de-identified information	R9-22-512(B)						R9-22-512(B) permits disclosure of "summary information" and other information that does not identify the applicant or recipient.
	(e) Disclosures to business associates	12-2292(B) 12-2294 (B)(6) 12-2294 (B)(7)				Qualified service organization disclosures permitted. 42 CFR 2.11, 42 CFR 2.12(c)(4)		
	(f) Deceased individuals					General rules apply. 42 CFR 2.15, consent must be obtained, 42 CFR 2.15(b)(2).		

Rule #	Description	State Law Reference/Description	Status	Title XIX Medicaid Reference/Description	Status	Federal Substance Abuse Confidentiality Reference/Description*	Status	Analysis
	(g) Personal representatives - Applicable to Minors, others	12-2293(B) 12-2293(D) 12-2294(B)(8) 12-2294(C) 12-2802(A)(3) 12-2802(E) Dec-03 13-1413 25-403(H) 36-509(A)(3) 36-509(A)(3) 36-661(2) 36-663 36-664(A)(1) 44-132 44-132.01 44-133.01 R9-22-512(D)(4)	State law prevails with respect to whether, and under what conditions, a minor has access to records; however, if the minor has authority to consent to treat, then the minor (and not the custodian) has the rights provided under the Privacy Rule.			Can seek parental consent to treatment of a minor ONLY if minor lacks capacity or has consented. 42 CFR 2.14 (c)(2). 42 CFR 2.14; Guardian if person incompetent, 42 CFR 2.15(a)(1).	More stringent for minors	R9-22-512(D)(4) permits disclosure to unemancipated minors with the written permission of the legal custodian.

Rule #	Description	State Law Reference/Description	Status	Title XIX Medicaid Reference/Description	Status	Federal Substance Abuse Confidentiality Reference/Description*	Status	Analysis
	(j) Disclosures by whistleblowers and workforce member crime victims					Only if crime on program premises or against program staff, 42 CFR 2.12(c)(5); ** Prohibited to initiate or substantiate a criminal charge. §290dd-2(c)..	more stringent than HIPAA	
164.504	Uses and disclosures: organizational requirements.							
	(b) Health care	R9-22-512; R9-				42 CFR 2.12(c)(3).	both	R9-22-512;

	(e) Business associate contracts	12-2292 (B)						
	http://www.bricker.com/attser/v/practice/hcare/hipaa/164.504e.asp	R9-22-512 Chapter 22 Part A Release of Safeguarded Information by the Administration and Contractors; R9-30- 403.C.10; R9- 30-512						
		R9-30-404.B.1						
		R9-30-407-D						
		R9-22-606; R9- 28-606;						
		12-2294(B)(6)						
		12-2294(B)(7)						
		12-2802(F)						
164.506	Consent for uses or disclosures to carry out treatment, payment, and health care operations							

Rule #	Description	State Law Reference/Description	Status	Title XIX Medicaid Reference/Description	Status	Federal Substance Abuse Confidentiality Reference/Description*	Status	Analysis
	(a) Permitted Uses and Disclosures	R9-22-512.E; R9-27-507A-G HCG Release of Safeguarded Information; R9-30-512.E; R9-27-504; R9-31-512				to patient 42 CFR 2.23(a).; To persons who set participation as a condition of a criminal proceeding, 42 CFR 2.35.		
		12-2294(B)(6)						
		12-2294(B)(7)						
		12-2294(B)(9)						
		12-2802 (A) (2), 12-2802 (A) (6), 12-2802 (A) (8), 12-2802 (A) (10),						
		12-2802 (A) (11),						
		36-509(A)(1)						
		36-509(A)(2)						
		36-664(A)(3)						
		36-664(A)(4)						
		36-664(A)(5)						
		36-664(A)(6)						

Rule #	Description	State Law Reference/Description	Status	Title XIX Medicaid Reference/Description	Status	Federal Substance Abuse Confidentiality Reference/Description*	Status	Analysis
	http://www.bricker.com/attser/v/practice/hcare/hipaa/164.506a.asp					42 CFR 2.33 requires prior consent in some cases. §290dd-2(b)(1); 42 CFR 2.22(1), 42 CFR 2.33.	several provisions of laws are more stringent than HIPAA regarding consent or authorization needed	
	(b) Consent permitted for use and disclosure	12-2292(B) 12-2294(B)				42 CFR 2.64(a) 2.31(a)(8)		
						To medical personnel in emergency, §290dd-2(b)(2)(A), 42 CFR 2.22(3); 42 CFR 2.51.42 CFR .		
164.508	Uses and disclosures for which an authorization is required.							

<u>Rule #</u>	<u>Description</u>	<u>State Law Reference/Description</u>	<u>Status</u>	<u>Title XIX Medicaid Reference/Description</u>	<u>Status</u>	<u>Federal Substance Abuse Confidentiality Reference/Description*</u>	<u>Status</u>	<u>Analysis</u>
	(a) Authorizations for Uses and Disclosures	R9-22-512.E .2.c; R9-27-507A-G HCG Release of Safeguarded Information; R9-30-512.E; R9-31-512				42 CFR 2.33 requires prior authorization in some cases.	Consent and authorizatio n mean the same in 42 CFR, Part 2; authorizatio n consistent, HIPAA rules for form can apply, must obtain for most disclosures , more stringent than HIPAA	
		12-2294 (B)(3)						
		12-2294 (B)(9)						
		12-2802(A)(2)						
		12-2802(A)(7)						
		36-509(A)(1)						
		36-509(A)(2)						
		36-509(A)(3)						
		36-509(A)(10)						
		36-509(A)(13)						
		36-664(A)(10)						
		36-664(E)						

<u>Rule #</u>	<u>Description</u>	<u>State Law Reference/Description</u>	<u>Status</u>	<u>Title XIX Medicaid Reference/Description</u>	<u>Status</u>	<u>Federal Substance Abuse Confidentiality Reference/Description*</u>	<u>Status</u>	<u>Analysis</u>
	(b) General requirements	R9-22-512.E.2.c; R9-27-507A-G HCG Release of Safeguarded Information; R9-30-512.E; R9-31-512						
164.51	Uses and disclosures requiring an opportunity for the individual to agree or to object.			42 CFR 431.306(d)				42 CFR 431.306(d) states that the Medicaid agency must obtain permission "whenever possible" before disclosing information to "outside sources" except in emergency situations, or to verify eligibility or payment.
	General Rule	R9-22-512.E.2.a&d						

<u>Rule #</u>	<u>Description</u>	<u>State Law Reference/Description</u>	<u>Status</u>	<u>Title XIX Medicaid Reference/Description</u>	<u>Status</u>	<u>Federal Substance Abuse Confidentiality Reference/Description*</u>	<u>Status</u>	<u>Analysis</u>
	(a) Uses and disclosures for facility directories			42 CFR 431.302		To a central registry and similar facilities within 200 miles, 42 CFR 2.34; Can disclose client's presence (to anyone) if the facility is not exclusively for use by abusers, 42 CFR 2.13(c)(1).		Not permitted without patient consent – under 42 CFR 431.302, this is not a purpose directly related to the administration of the program.
	(b) Uses and disclosures for involvement in the individual's care and notification purposes	R9-22-512; R9-27-504; R9-30-512; R9-31-512		42 CFR 431.302		Can disclose client's presence (to anyone) if the facility is not exclusively for use by abusers, 42 CFR 2.13(c)(1).		Not permitted without patient consent – under 42 CFR 431.302, this is not a purpose directly related to the administration of the program.
		36-509(A)(8)						

<u>Rule #</u>	<u>Description</u>	<u>State Law Reference/Description</u>	<u>Status</u>	<u>Title XIX Medicaid Reference/Description</u>	<u>Status</u>	<u>Federal Substance Abuse Confidentiality Reference/Description*</u>	<u>Status</u>	<u>Analysis</u>
164.512	Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required.	R9-22-512; R9-27-504; R9-30-512; R9-31-512						
	(a) Uses and disclosures required by law	R9-22-512.F.3 12-2282 (C)(4) (D) 36-509(A)(2) 36-509(A)(11) 36-664(A)(7) 36-664(A)(8) 36-2903(1) 36-2918.01 36-2992 		42 CFR 431.301 et seq.		Within Uniformed Services (Military) and VA, §290dd-2(e)	required by law; consistent with HIPAA	Even if permitted by other law, disclosure is prohibited by 42 CFR 431.301 et seq., without patient consent under 42 CFR 431.306 (d), unless disclosure is for a purpose related to the administration of the program.

<u>Rule #</u>	<u>Description</u>	<u>State Law Reference/Description</u>	<u>Status</u>	<u>Title XIX Medicaid Reference/Description</u>	<u>Status</u>	<u>Federal Substance Abuse Confidentiality Reference/Description*</u>	<u>Status</u>	<u>Analysis</u>
	(b) Uses and disclosures for public health activities	12-2802(A)(5) 12-2802(A)(9) 36-664(A)(7) 36-664(K) R9-27-513; R9-27-507 and 514; R9-30-512.F		42 CFR 431.306(e)		Child abuse or neglect, 42 CFR 2.22.; FDA If approved drug causes harm, 42 CFR 2.51(b)		42 CFR 431.306(e), Medicaid policies regarding "purposes directly related to the administration of the program" and consent apply to government agencies.
	(c) Disclosures about victims of abuse, neglect, or domestic violence			42 CFR 431.306(e)		Abuse, neglect, 42 CFR 2.12(c)(6).	required by law - consistent	42 CFR 431.306(e), Medicaid policies regarding "purposes directly related to the administration of the program" and consent apply to government agencies.

Rule #	Description	State Law Reference/Description	Status	Title XIX Medicaid Reference/Description	Status	Federal Substance Abuse Confidentiality Reference/Description*	Status	Analysis
	(d) Uses and disclosures for health oversight activities	36-509(A)(9)		42 CFR 431.306(e)		42 CFR 2.66.		42 CFR 431.306(e), Medicaid policies regarding "purposes directly related to the administration of the program" and consent apply to government agencies.
		36-664(1)						
		R9-22-512.F.3.a&b and 4 AHCCCS Program matters only; R9-27-513; R9-27-507 and 514; R9-30-512.F; R9-31-512						
	(e) Disclosures for judicial and administrative proceedings	12-2282(A)(B)(C)	AHCCCS State code is more stringent	42 CFR 431.306(f)		Prohibited to initiate or substantiate a criminal charge. §290dd-2(c). To persons who set participation as a condition of a criminal proceeding, 42 CFR 2.35.;	parts are more stringent	
		(D)(E)(F)						
		12-2285(B)						

		12-2802(B)						
		12-2802(C)						
		36-509(A)(4)						
		36-664(A)(9)						
			Consistent, applies in part					
		R9-22-512.F.3.; R9-27-513; R9- 27-507 and 514; R9-30- 512.F; R9-31- 512						

Rule #	Description	State Law Reference/Description	Status	Title XIX Medicaid Reference/Description	Status	Federal Substance Abuse Confidentiality Reference/Description*	Status	Analysis
	http://www.bricker.com/attser/v/practice/hcare/hipaa/164.512e.asp					Good cause shown, §290dd-2(b)(2)(C); 42 CFR 2.22(2), 42 CFR 2.61 – 2.67.		
	(f) Disclosures for law enforcement purposes	12-2282(C)(2)(3)	For program purposes only; R-9 more stringent	42 CFR 431.306(e)	Title XIX more stringent	With restrictions, 42 CFR 2.61(a). Prohibited to initiate or substantiate a criminal charge. §290dd-2(c).	more stringent than HIPAA requirements	42 CFR 431.306(e), Medicaid policies regarding “purposes directly related to the administration of the program” and consent apply to government agencies.
		36-509(A)(7)						
		36-664(A)(9)						
		36-664(J)						
		12-2294(B)(8)						

<u>Rule #</u>	<u>Description</u>	<u>State Law Reference/Description</u>	<u>Status</u>	<u>Title XIX Medicaid Reference/Description</u>	<u>Status</u>	<u>Federal Substance Abuse Confidentiality Reference/Description*</u>	<u>Status</u>	<u>Analysis</u>
	(g) Uses and disclosures about decedents	12-2802(A)(7) 36-664(A)(5)	12-2294 appears to be pre-empted.			For vital statistics, cause of death, 42 CFR 2.15(b)(1).		45 CFR 164.512(g) limits disclosures about decedents to coroners, medical examiners, and funeral directors pre-empting state law permitting disclosure to personal representatives of the estate or family members (except pursuant to court order under 45 CFR 164.512(e)).

<u>Rule #</u>	<u>Description</u>	<u>State Law Reference/Description</u>	<u>Status</u>	<u>Title XIX Medicaid Reference/Description</u>	<u>Status</u>	<u>Federal Substance Abuse Confidentiality Reference/Description*</u>	<u>Status</u>	<u>Analysis</u>
	(h) Uses and disclosures for cadaveric organ, eye or tissue donation purposes	12-2802(A)(4)(5) 36-509(A)(5)				same as g		
	(i) Uses and disclosures for research purposes	36-664(A)(5) 36-509(A)(7)		42 CFR 431.301 et seq.		42 CFR 2.52.		Identifiable information may not be disclosed for purposes other than those directly related to the administration of the program unless consent is obtained consistent with 42 CFR 431.306.
	http://www.bricker.com/attser/v/practice/hcare/hipaa/164.512i.asp	R9-22-512.F.1,2 and 5; R9-27-513; R9-27-507 and 514; R9-30-512.F; R9-31-512				Deidentified, §290dd-2(b)(2)(B).		

Rule #	Description	State Law Reference/Description	Status	Title XIX Medicaid Reference/Description	Status	Federal Substance Abuse Confidentiality Reference/Description*	Status	Analysis
	(j) Uses and disclosures to avert a serious threat to health or safety			42 CFR 431.301 et seq.		Need court order for confidential communication, 42 CFR 2.63(a)(1).	more stringent than HIPAA	Identifiable information may not be disclosed for purposes other than those directly related to the administration of the program unless consent is obtained consistent with 42 CFR 431.306.
	(k) Uses and disclosures for specialized government functions	36-509(A)(6)		42 CFR 431.306(e)		§290dd-2(e) as above		42 CFR 431.306(e), Medicaid policies regarding "purposes directly related to the administration of the program" and consent apply to government agencies.
		36-664(A)(11)						

Rule #	Description	State Law Reference/Description	Status	Title XIX Medicaid Reference/Description	Status	Federal Substance Abuse Confidentiality Reference/Description*	Status	Analysis
	http://www.bricker.com/attser/v/practice/hcare/hipaa/164.512k.asp					To Armed Forces, 42 CFR 2.12(c)(2)		
	(l) Disclosures for workers compensation	12-2802(A)(4)		42 CFR 431.306(e)		.		42 CFR 431.306(e), Medicaid policies regarding "purposes directly related to the administration of the program" and consent apply to government agencies.
164.514	Other requirements relating to uses and disclosures of protected health information.	36-664(A)(6)						
	(a) De-identification of PHI	R9-22-512.A, R9-27-507; R9-30-512; R9-31-512						

Rule #	Description	State Law Reference/ Description	Status	Title XIX Medicaid Reference/ Description	Status	Federal Substance Abuse Confidentiality Reference/ Description*	Status	Analysis
	(b) Requirements for de-identification of PHI							
	(f) Uses and disclosures for fundraising	R9-22-512.3.c Law Enforcement official with statutory authority to obtain info, R9-31-512		42 CFR 431.301 et seq.				Identifiable information may not be disclosed for purposes other than those directly related to the administration of the program unless consent is obtained consistent with 42 CFR 431.306.
	(g) Uses and disclosures for underwriting and related purposes					Mgmt, financial, or program audit §290dd-2(b)(2)(B), 42 CFR 2.22(3), 2.53.		

<u>Rule #</u>	<u>Description</u>	<u>State Law Reference/Description</u>	<u>Status</u>	<u>Title XIX Medicaid Reference/Description</u>	<u>Status</u>	<u>Federal Substance Abuse Confidentiality Reference/Description*</u>	<u>Status</u>	<u>Analysis</u>
	(h) Verification requirements		More specific					
164.52	Notice of privacy practices for protected health information.							
	(a) Right to notice of privacy practices			42 CFR 431.304		Notice content, 42 CFR 2.22. ; By court order, to individual and record holder, 42 CFR 2.64(b).		Medicaid rule not inconsistent with HIPAA Privacy Rule; Privacy Rule is more specific.
	(b) Content of notice of privacy practices			42 CFR 431.304				Medicaid rule not inconsistent with HIPAA Privacy Rule; Privacy Rule is more specific.

Rule #	Description	State Law Reference/Description	Status	Title XIX Medicaid Reference/Description	Status	Federal Substance Abuse Confidentiality Reference/Description*	Status	Analysis
	(c) Provision of notice of privacy practices			42 CFR 431.304				Medicaid rule not inconsistent with HIPAA Privacy Rule; Privacy Rule is more specific.
164.522	Rights to request privacy protection for protected health information.	R9-22-512.(D); R9-27-507; R9-30-512; R9-31-512						
164.524	Access of individuals to protected health information.	12-2293 (A) (C)						
	(a) Access to PHI	12-2802(A)(1)				General, 42 CFR 2.23(a).		
		12-2294(E)						
		Dec-95						
		36-507						
		36-664(A)(1)						

Rule #	Description	State Law Reference/Description	Status	Title XIX Medicaid Reference/Description	Status	Federal Substance Abuse Confidentiality Reference/Description*	Status	Analysis
164.52 6	Amendment of protected health information.	36-664(H)						
164.52 8	Accounting of disclosures of protected health information.							
	(a) Right to an accounting of disclosures							
164.53	Administrative requirements.							
	(c) Safeguards					Records maintained in locked container, 42 CFR 2.16.		
	http://www.bricker.com/attser/v/practice/hcare/hipaa/164.530c.asp					Consent expires,		
	(d) Complaints to the covered entity					2.31(a)(9).		

<u>Rule #</u>	<u>Description</u>	<u>State Law Reference/Description</u>	<u>Status</u>	<u>Title XIX Medicaid Reference/Description</u>	<u>Status</u>	<u>Federal Substance Abuse Confidentiality Reference/Description*</u>	<u>Status</u>	<u>Analysis</u>
	(e) Sanctions	R9-22-606; R9-28-606; R9-30-407,408				Suspend or revoke federal support if output facility or hospital does not comply after given opportunity to do so. 42 USC 290dd-1(b)(1).	more prescriptive than HIPAA, which requires sanctions, but not specific ones	
	http://www.bricker.com/attser/v/practice/hcare/hipaa/164.530e.asp					Up to \$500 for the first offense, \$5,000 for each subsequent offense, 42 CFR 2.4.		
	(f) Mitigation of harmful effect							

<u>Rule #</u>	<u>Description</u>	<u>State Law Reference/Description</u>	<u>Status</u>	<u>Title XIX Medicaid Reference/Description</u>	<u>Status</u>	<u>Federal Substance Abuse Confidentiality Reference/Description*</u>	<u>Status</u>	<u>Analysis</u>
	(j) Documentation					Purge patient identifying info if program discontinues or is acquired by another program, unless consent to transfer or other legal req't. Retained in sealed envelopes until legal req't date has run, then records are destroyed. 42 CFR 2.19.		
164.53 2	Transition requirements.							
164.53 4	Compliance dates for initial implementation of the privacy standards.							
<u>Rule #</u>	<u>Description</u>	<u>State Law Reference/Description</u>	<u>Status</u>	<u>Title XIX Medicaid Reference/Description</u>	<u>Status</u>	<u>Federal Substance Abuse Confidentiality Reference/Description*</u>	<u>Status</u>	<u>Analysis</u>

						* Public Health Service Act, Title 42, section 290dd-3 of the United State Code (CFR 42-2)		
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5.0 INTERACTION WITH OTHER FEDERAL LAWS

In addition to determining the extent to which HIPAA preempts, or is preempted by, state statutes, administrative rules and common law, AHCCCS and other covered entities need to determine how the HIPAA Privacy Regulations relate to compliance with other applicable federal laws. Legal theories and case law may need to be developed as well. This section identifies some of the issues raised by these additional preemption considerations.

The preamble to the Final Privacy Rule of December, 2000 discusses some of the other federal statutes and regulations governing privacy that affect covered entities, and offers some guidance for assessing the interaction between them. Federal laws discussed in the preamble include the

- ❑ Privacy Act of 1974
- ❑ Freedom of Information Act
- ❑ Substance Abuse Confidentiality Requirements
- ❑ Employee Retirement Income Security Act of 1974 (“ERISA”)
- ❑ Family Educational Rights and Privacy Act
- ❑ Graham-Leach-Bliley Act,
- ❑ Federally Funded Health Programs Requirements
- ❑ Food, Drugs and Cosmetic Act,
- ❑ Clinical Laboratory Improvement Act (“CLIA”),
- ❑ Other Mandatory Federal or State Laws and Disability Nondiscrimination Laws.

(See Appendix B for brief summaries of these laws as they appear in the preamble of the Privacy Regulations.)

DHHS, in the preamble, indicates that there should be few instances where existing federal statutes and rules will conflict with the Privacy Regulations. This is due to the mostly permissive nature of the Privacy Regulations, in which authorizations may be used when required by other law, and the stipulation of “required by other laws” is allowed for permitted uses and disclosures. The following is excerpted from pages 82481-82482:

“There should be few instances in which conflicts exist between a statute or regulation and the rules below. For example, if a statute permits a covered entity to disclose protected health information and the [Privacy Regulations] permit such a disclosure, no conflict arises; the covered entity could comply with both and choose whether or not to disclose the information. In instances in which a potential conflict appears, we would attempt to resolve it so that both laws applied. For example, if a statute or regulation permits dissemination of protected health information, but the rules below prohibit the use or disclosure without an authorization, we believe a covered entity would be able to comply with both because it could obtain an authorization under § 164.508 before disseminating the information under the other law.”

“Many apparent conflicts will not be true conflicts. For example, if a conflict appears to exist because a previous statute or regulation requires a specific use or disclosure of protected health information that the rules below appear to prohibit, the use or disclosure pursuant to that statute or regulation would not be a violation of the privacy regulation because § 164.512(a) permits covered entities to use or disclose protected health information as required by law.”

It is important to note that employers are not covered entities under the privacy regulation. Many employers, however, are subject to the federal disability nondiscrimination laws and, therefore, must protect the confidentiality of all medical information concerning their applicants and employees.

Given the above discussion from the preamble, and the myriad of individual situations where interpretation of the interaction of other federal laws and HIPAA regulation will be needed on an ongoing basis, AHCCCS and FourThought Group decided to focus attention on the two federal laws that have the most impact on its operations and policies/procedures. These laws are the Social Security Act, Title XIX, Medicaid “safeguarding” regulations (42 CFR 431.300 et seq.) and the Public Health Service Act, Federal Alcohol and Other Drug Confidentiality Law and Regulations (CFR 42, Part 2) Section 3.2 contains the matrix including the crosswalk of these two laws and the following sections discuss issues arising out of the crosswalk in narrative form.

4.1 Safeguarding Information under Medicaid & AHCCCS (Is this supposed to be 5.1 and the following be 5.2?)

Both the federal regulations pertaining to Medicaid² and the state administrative code provisions relating to the AHCCCS³ program limit the use and disclosure of individual information obtained by the agency through the program (the “safeguarding” provisions).

The state rule follows the substance of the federal regulations. Both generally restrict the use and disclosure of personal identifiers, financial information, and medical information to purposes directly related to the administration of the program.⁴ The rule defines “purposes directly related to the administration of the program.”⁵ The rule requires disclosure to the applicant or recipient.⁶ Authorization from the applicant or recipient is required for disclosures for purposes other than those directly related to the administration of the program, and the rule defines the requirements for a valid authorization.⁷ Disclosures of

² 42 CFR 431.300 through 431.307

³ AAC R9-22-512 (acute services); AAC R9-27-507 (Health Care Group); AAC R9-28-514 (ALTCS); AAC R9-30-512 (Premium Sharing Program); and AAC R9-31-512 (KidsCare). The provisions are equivalent. For the sake of ease, reference are to the acute rule.

⁴ AAC R9-22-512(A) and (F); 42 CFR 431.302.

⁵ AAC R9-22-512(F)(1).

⁶ AAC R9-22-512(D).

⁷ AAC R9-22-512(E).

summary information and information that does not identify the applicant or recipient is permitted.⁸

In general, the Privacy Rule does not preempt the safeguarding provisions because those provisions are not contrary to the Privacy Rule. It is possible, in almost every instance, to comply with both the safeguarding provisions and the Privacy Rule. For instance, both the safeguarding provisions and the Privacy Rule specify the requirements for a valid authorization. While the criteria for an authorization under the Privacy Rule is more specific than the safeguarding provisions, the criteria do not conflict – an authorization form can be created to include the requirements of both rules.

There are two key aspects of the safeguarding requirements that should be considered when the state law is compared to the Privacy Rule. First, the safeguarding provisions apply to more than protected health information as defined in the privacy rule; that is, the safeguarding provisions apply to personal identifiers as well as information regarding “social and economic conditions or circumstances.” Much of this information may have been gathered in connection with the eligibility determination process and may have nothing to do directly with the delivery of, or payment for health services. Since the safeguarding provisions and the Privacy Rule can coexist, the release of such additional information is still subject to the requirements of the state law.

Second, the safeguarding provisions restrict acceptable uses and disclosures to a greater extent than the Privacy Rule. Many of the disclosures that are permissible (but not mandatory) under the Privacy Rule are limited by the safeguarding provisions restriction to purposes directly related to the administration of the program. For instance, the Privacy Rule states that a covered entity may, under limited circumstances, use and disclose protected health information for purposes of fundraising⁹; however, since fundraising is not directly related to the administration of the AHCCCS program, such a disclosure is prohibited by the safeguarding provisions even if it is permissible under the Privacy Rule.

As a simple test, the AHCCCS Administration, its contractors, and its providers should always ask themselves the question “is the contemplated use or disclosure directly related to the administration of the AHCCCS program?” even if the Privacy Rule permits the use or disclosure.

5.1 Federal Alcohol and Other Drug Confidentiality Law (Law – CFR 42, Part 2)

The federal drug and alcohol confidentiality regulations are predicated on the view that people with substance abuse problems are more likely to seek, and

⁸ AAC R9-22-512(B).

⁹ 45 CFR 164.514(f).

succeed at, treatment if they are assured that their identity and need for treatment will not be disclosed unnecessarily. It is also widely held in the public health field that strict adherence to confidentiality is essential to the success of drug abuse prevention programs. That view of protection extends not only to current patients, but former patients, as well. In keeping with that view, the regulations restrict both the disclosure and use of information about individuals in federally assisted drug and alcohol programs (“federally-assisted” is broadly defined and includes federally conducted or funded programs, federally licensed or certified programs, and programs that are tax exempt.) This impacts AHCCCS in that the Medicaid program pays for some substance abuse treatment services in these programs and may need individually identifiable information in order to conduct treatment, payment, health care operations, and/or health care oversight.

CFR 42, Part 2 restricts the disclosure and use of “patient identifying” information about individuals in substance abuse treatment. This is defined as information that reveals that a person is receiving, has received, or has applied for substance abuse treatment. This definition is more inclusive than HIPAA’s definition. The protection is not the individual’s identity per se, but rather his or her identity as a participant in, or applicant for, substance abuse treatment.

The regulations apply to the individual or program in possession of the information, people or entities receiving it, and those who seek the information. The program may not release it without patient authorization or as otherwise permitted (very limited circumstances) and anyone who receives it may not re-disclose it without patient consent/authorization nor use it except for limited purposes. These regulations are stricter than most other confidentiality rules, including HIPAA. State law may be more restrictive, but cannot override the federal regulations.

The impact on AHCCCS is that in cases where this law governs the privacy practices of a provider, a valid authorization (valid under both HIPAA and this law) will need to be obtained from a patient.

Specific provisions are cross-walked with HIPAA in the Matrix in Section 3.2, with comments as needed.

6.0 NEXT STEPS

The magnitude of the effects and implications of the HIPAA Privacy Rule preemption provisions on AHCCCS compliance are not foreseeable at this time. As policies and procedures are developed in Phase III, it will be essential to conduct an ongoing review and build in flexibility to deal with specific instances particularly regarding

- Minors and permitted/restricted disclosures to parents or guardians

- ❑ The potential need to obtain patient authorizations when requesting disclosures of individually identifiable information from licensed substance abuse treatment programs
- ❑ Use and disclosures of information on members receiving mental health services
- ❑ Use and disclosures regarding genetic testing
- ❑ Use and disclosures regarding HIV/AIDS testing and information on members with HIV/AIDS and other communicable diseases such as sexually transmitted diseases (STDs)
- ❑ Overlaying the more restrictive disclosure provisions of the federal and state Medicaid laws with the permitted disclosures under HIPAA Privacy §164.512

Already subject to debate and analysis are HIPAA's relationship to state laws, other federal laws regulating privacy and international privacy standards; HIPAA's affect on health plans or programs that are not subject to HIPAA; and the effect of developing legal theories affecting privacy issues, including preemption issues. The Preamble to the Final Privacy Rule of December 2000, in its discussion under *Other Mandatory Federal or State Laws*, explains that covered entities should rely on the provisions under § 164.512 (a) allowing for disclosures as permitted by other law for those laws requiring a covered entity to disclose a specific type of information. DHHS goes on to state

"When a covered entity is faced with a question as to whether the privacy regulation would prohibit the disclosure of protected health information... pursuant to a federal law, the covered entity should determine if the disclosure is required by that law. In other words, it must determine if the disclosure is mandatory rather than merely permissible. If it is mandatory, a covered entity may disclose the protected health information pursuant to § 164.512(a), which permits covered entities to disclose protected health information without an authorization when the disclosure is required by law. If the disclosure is not required (but only permitted) by the federal law, the covered entity must determine if the disclosure comes within one of the other permissible disclosures. If the disclosure does not come within one of the provisions for permissible disclosures, the covered entity must obtain an authorization from the individual who is the subject of the information or de-identify the information before disclosing it. If another federal law prohibits a covered entity from using or disclosing information that is also protected health information, but the privacy regulation permits the use or disclosure, a covered entity will need to comply with the other federal law and not use or disclose the information."

There may be other preemption efforts underway in both Arizona and in the federal government that may further the analysis contained in this document. The AZHHA is projected to update their analysis in early 2003, but it may be of limited usefulness to AHCCCS, since its focus is more provider- oriented and the current one did not review the AAC governing AHCCCS. The Arizona Department of Health Services/Behavioral Health Services has stated that they are planning to conduct a preemption analysis focusing on the interaction between HIPAA Privacy and state and federal mental health and substance abuse laws. It is unclear when that project will be completed. On the federal level, the Substance Abuse and Mental Health Services Administration (SAMHSA) has stated at the National Governor's Conference that it is completing a preemption analysis and the Centers for Medicare and Medicaid Services (CMS) has

been requested repeatedly to conduct one for the Medicaid laws. CMS has said it would get back to the states on that issue. If the federal agencies were to conduct and publish those preemption analyses, rather than have 50 different interpretations conducted by 50 state entities, it would be very helpful in Phase III of the FourThought Group and AHCCCS Privacy and Security Project.

In summary, efforts to consider the preemption and interaction of state and other federal laws with HIPAA Privacy will be ongoing and dynamic during the course of Phase III. It will be necessary to consider not only the findings presented in this report, but also to monitor, both statewide and nationally, other interpretations as they emerge. As policies and procedures are developed to comply with HIPAA, it will be important to include provisions for exceptions and case-by-case analysis, particularly with regard to the use of member authorizations to disclose protected health information outside of AHCCCS. FourThought Group will continue to work with AHCCCS OLA and the Implementation Workgroup to integrate legal preemption factors in other activities designed to achieve compliance with the HIPAA Privacy Regulations by April 14, 2003.

APPENDIX A: REFERENCES

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Public Health Service Act, Title 42, section 290dd-3 of the United State Code (CFR 42-2)
– Federal Alcohol and Other Drug Confidentiality Law and Regulations

APPENDIX B

Federal Laws Summary From December 2000 Preamble

Excerpted from 65 FR pp. 82482 – 82486

Privacy Act of 1974

The Privacy Act of 1974, 5 U.S.C. 552a, prohibits disclosures of records contained in a system of records maintained by a federal agency (or its contractors) without the written request or consent of the individual to whom the record pertains. This general rule is subject to various statutory exceptions. In addition to the disclosures explicitly permitted in the statute, the Privacy Act permits agencies to disclose information for other purposes compatible with the purpose for which the information was collected by identifying the disclosure as a “routine use” and publishing notice of it in the Federal Register. The Act applies to all federal agencies and certain federal contractors who operate Privacy Act systems of records on behalf of federal agencies.

Some federal agencies and contractors of federal agencies that are covered entities under the Privacy Regulations are subject to the Privacy Act. These entities must comply with all applicable federal statutes and regulations. For example, if the privacy regulation permits a disclosure, but the disclosure is not permitted under the Privacy Act, the federal agency may not make the disclosure. If, however, the Privacy Act allows a federal agency the discretion to make a routine use disclosure, but the privacy regulation prohibits the disclosure, the federal agency will have to apply its discretion in a way that complies with the regulation. This means not making the particular disclosure.

The Freedom of Information Act

FOIA, 5 U.S.C. 552, provides for public disclosure, upon the request of any person, of many types of information in the possession of the federal government, subject to nine exemptions and three exclusions. For example, Exemption 6 permits federal agencies to withhold “personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.” 5 U.S.C. 552(b)(6).

Uses and disclosures required by FOIA come within § 164.512(a) of the privacy regulation that permits uses or disclosures required by law if the uses or disclosures meet the relevant requirements of the law. Thus, a federal agency must determine whether it may apply an exemption or exclusion to redact the protected health information when responding to a FOIA request. When a FOIA request asks for documents that include protected health information, we believe the agency, when appropriate, must apply Exemption 6 to preclude the release of medical files or otherwise redact identifying details before disclosing the remaining information.

We offer the following analysis for federal agencies and federal contractors who operate Privacy Act systems of records on behalf of federal agencies and must comply with FOIA and the privacy regulation. If presented with a FOIA request that would result in the disclosure of protected health information, a federal agency must first determine if FOIA requires the disclosure or if an exemption or exclusion would be appropriate. We believe that generally a disclosure of protected health information, when requested under FOIA, would come within FOIA Exemption 6. We recognize, however, that the application of this exemption to information about deceased individuals requires a different analysis than that applicable to living individuals because, as a general rule, under the Privacy Act, privacy rights are extinguished at death. However, under FOIA, it is entirely appropriate to consider the privacy interests of a decedent’s survivors under Exemption 6. See Department of Justice FOIA Guide 2000, Exemption 6: Privacy Considerations. Covered entities subject to FOIA must evaluate each disclosure on a case-by-case basis, as they do now under current FOIA procedures.

Federal Substance Abuse Confidentiality Laws and Rules

The federal confidentiality of substance abuse patient records statute, section 543 of the Public Health Service Act, 42 U.S.C. 290dd-2, and its implementing regulation, 42 CFR Part 2, establish confidentiality requirements for patient records that are maintained in connection with the performance of any federally-assisted specialized alcohol or drug abuse program. Substance abuse programs are generally programs or personnel that provide alcohol or drug abuse treatment, diagnosis, or referral for treatment. The term “federally-assisted” is broadly defined and includes federally conducted or funded programs, federally licensed or certified programs, and programs that are tax exempt. Certain exceptions apply to information held by the Veterans Administration and the Armed Forces.

There are a number of health care providers that are subject to both these rules and the substance abuse statute and regulations. In most cases, a conflict will not exist between these rules. These Privacy Regulations permit a health care provider to disclose information in a number of situations that are not permitted under the substance abuse regulation. For example, disclosures allowed, without patient authorization, under the Privacy Regulations for law enforcement, judicial and administrative proceedings, public health, health oversight, directory assistance, and as required by other laws would generally be prohibited under the substance abuse statute and regulation. However, because these disclosures are permissive and not mandatory, there is no conflict. An entity would not be in violation of the Privacy Regulations for failing to make these disclosures.

Similarly, provisions in the substance abuse regulation provide for permissive disclosures in case of medical emergencies, to the FDA, for research activities, for audit and evaluation activities, and in response to certain court orders. Because these are permissive disclosures, programs subject to both the Privacy Regulations and the substance abuse rule are able to comply with both rules even if the Privacy Regulations restrict these types of disclosures. In addition, the Privacy Regulations generally require that an individual be given access to his or her own health information. Under the substance abuse regulation, programs may provide such access, so there is no conflict.

The substance abuse regulation requires notice to patients of the substance abuse confidentiality requirements and provides for written consent for disclosure. While the Privacy Regulations have requirements that are somewhat different, the program may use notice and authorization forms that include all the elements required by both regulations. The substance abuse rule provides a sample notice and a sample authorization form and states that the use of these forms would be sufficient. While these forms do not satisfy all of the requirements of the privacy regulation, there is no conflict because the substance abuse regulation does not mandate the use of these forms.

Employee Retirement Income Security Act of 1974

ERISA was enacted in 1974 to regulate pension and welfare employee benefit plans established by private sector employers, unions, or both, to provide benefits to their workers and dependents. Under ERISA, plans that provide “through the purchase of insurance or otherwise ... medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, [or] death” are defined as employee welfare benefit plans. 29 U.S.C. 1002(1). In 1996, HIPAA amended ERISA to require portability, nondiscrimination, and renewability of health benefits provided by group health plans and group health insurance issuers. Numerous, although not all, ERISA plans are covered under the rules proposed below as “health plans.”

Section 514(a) of ERISA, 29 U.S.C. 1144(a), preempts all state laws that “relate to” any employee benefit plan. However, section 514(b) of ERISA, 29 U.S.C. 1144(b)(2)(A), expressly saves from preemption state laws that regulate insurance. Section 514(b)(2)(B) of ERISA, 29 U.S.C. 1144(b)(2)(B), provides that an ERISA plan is deemed not to be an insurer for the purpose of regulating the plan under the state insurance laws. Thus, under the deemed clause, states may not treat ERISA plans as insurers subject to direct regulation by state law. Finally, section 514(d) of ERISA, 29 U.S.C. 1144(d), provides that ERISA does not “alter, amend, modify, invalidate, impair, or supersede any law of the United States.”

We considered whether the preemption provision of section 264(c)(2) of HIPAA would give effect to state

laws that would otherwise be preempted by section 514(a) of ERISA. As discussed above, our reading of the statutes together is that the effect of section 264(c)(2) is only to leave in place state privacy protections that would otherwise apply and that are more stringent than the federal privacy protections. Many health plans covered by the privacy regulation are also subject to ERISA requirements. Our discussions and consultations have not uncovered any particular ERISA requirements that would conflict with the rules.

Federal Education Rights and Privacy Act

FERPA, as amended, 20 U.S.C. 1232g, provides parents of students and eligible students (students who are 18 or older) with privacy protections and rights for the records of students maintained by federally funded educational agencies or institutions or persons acting for these agencies or institutions. We have excluded education records covered by FERPA, including those education records designated as education records under Parts B, C, and D of the Individuals with Disabilities Education Act Amendments of 1997, from the definition of protected health information. For example, individually identifiable health information of students under the age of 18 created by a nurse in a primary or secondary school that receives federal funds and that is subject to FERPA is an education record, but not protected health information. Therefore, the privacy regulation does not apply. We followed this course because Congress specifically addressed how information in education records should be protected in FERPA.

We have also excluded certain records, those described at 20 U.S.C. 1232g(a)(4)(B)(iv), from the definition of protected health information because FERPA also provided a specific structure for the maintenance of these records. These are records (1) of students who are 18 years or older or are attending post-secondary educational institutions, (2) maintained by a physician, psychiatrist, psychologist, or recognized professional or paraprofessional acting or assisting in that capacity, (3) that are made, maintained, or used only in connection with the provision of treatment to the student, and (4) that are not available to anyone, except a physician or appropriate professional reviewing the record as designated by the student. Because FERPA excludes these records from its protections only to the extent they are not available to anyone other than persons providing treatment to students, any use or disclosure of the record for other purposes, including providing access to the individual student who is the subject of the information, would turn the record into an education record. As education records, they would be subject to the protections of FERPA.

These exclusions are not applicable to all schools, however. If a school does not receive federal funds, it is not an educational agency or institution as defined by FERPA. Therefore, its records that contain individually identifiable health information are not education records. These records may be protected health information. The educational institution or agency that employs a school nurse is subject to our regulation as a health care provider if the school nurse or the school engages in a HIPAA transaction.

While we strongly believe every individual should have the same level of privacy protection for his/her individually identifiable health information, Congress did not provide us with authority to disturb the scheme it had devised for records maintained by educational institutions and agencies under FERPA. We do not believe Congress intended to amend or preempt FERPA when it enacted HIPAA. With regard to the records described at 20 U.S.C. 1232g(a)(4)(b)(iv), we considered requiring health care providers engaged in HIPAA transactions to comply with the privacy regulation up to the point these records were used or disclosed for purposes other than treatment. At that point, the records would be converted from protected health information into education records. This conversion would occur any time a student sought to exercise his/her access rights. The provider, then, would need to treat the record in accordance with FERPA's requirements and be relieved from its obligations under the privacy regulation. We chose not to adopt this approach because it would be unduly burdensome to require providers to comply with two different, yet similar, sets of regulations and inconsistent with the policy in FERPA that these records be exempt from regulation to the extent the records were used only to treat the student.

Gramm-Leach-Bliley Act

In 1999, Congress passed Gramm-Leach-Bliley (GLB), Pub. L. 106-102, which included provisions, section 501 et seq., that limit the ability of financial institutions to disclose "nonpublic personal information" about consumers to non-affiliated third parties and require financial institutions to provide

customers with their privacy policies and practices with respect to nonpublic personal information. In addition, Congress required seven agencies with jurisdiction over financial institutions to promulgate regulations as necessary to implement these provisions. GLB and its accompanying regulations define “financial institutions” as including institutions engaged in the financial activities of bank holding companies, which may include the business of insuring. See 15 U.S.C. 6809(3); 12 U.S.C. 1843(k). However, Congress did not provide the designated federal agencies with the authority to regulate health insurers. Instead, it provided states with an incentive to adopt and have their state insurance authorities enforce these rules. See 15 U.S.C. 6805. If a state were to adopt laws consistent with GLB, health insurers would have to determine how to comply with both sets of rules. Thus, GLB has caused concern and confusion among health plans that are subject to our privacy regulation. Although Congress remained silent as to its understanding of the interaction of GLB and HIPAA’s privacy provisions, the Federal Trade Commission and other agencies implementing the GLB privacy provisions noted in the preamble to their GLB regulations that they “would consult with HHS to avoid the imposition of duplicative or inconsistent requirements.” 65 Fed. Reg. 33646, 33648 (2000). Additionally, the FTC also noted that “persons engaged in providing insurance” would be within the enforcement jurisdiction of state insurance authorities and not within the jurisdiction of the FTC. *Id.*

Because the FTC has clearly stated that it will not enforce the GLB privacy provisions against persons engaged in providing insurance, health plans will not be subject to dual federal agency jurisdiction for information that is both nonpublic personal information and protected health information. If states choose to adopt GLB-like laws or regulations, which may or may not track the federal rules completely, health plans would need to evaluate these laws under the preemption analysis described in subpart B of Part 160.

Federally Funded Health Programs

These rules will affect various federal programs, some of which may have requirements that are, or appear to be, inconsistent with the requirements of these regulations. These programs include those operated directly by the federal government (such as health programs for military personnel and veterans) as well as programs in which health services or benefits are provided by the private sector or by state or local governments, but which are governed by various federal laws (such as Medicare, Medicaid, and ERISA).

Congress explicitly included some of these programs in HIPAA, subjecting them directly to the privacy regulation. Section 1171 of the Act defines the term “health plan” to include the following federally conducted, regulated, or funded programs: group plans under ERISA that either have 50 or more participants or are administered by an entity other than the employer who established and maintains the plan; federally qualified health maintenance organizations; Medicare; Medicaid; Medicare supplemental policies; the health care program for active military personnel; the health care program for veterans; the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); the Indian health service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.; and the Federal Employees Health Benefits Program. There also are many other federally conducted, regulated, or funded programs in which individually identifiable health information is created or maintained, but which do not come within the statutory definition of “health plan.” While these latter types of federally conducted, regulated, or assisted programs are not explicitly covered by part C of title XI in the same way that the programs listed in the statutory definition of “health plan” are covered, the statute may nonetheless apply to transactions and other activities conducted under such programs. This is likely to be the case when the federal entity or federally regulated or funded entity provides health services; the requirements of part C may apply to such an entity as a “health care provider.” Thus, the issue of how different federal requirements apply is likely to arise in numerous contexts.

There are a number of authorities under the Public Health Service Act and other legislation that contain explicit confidentiality requirements, either in the enabling legislation or in the implementing regulations. Many of these are so general that there would appear to be no problem of inconsistency, in that nothing in those laws or regulations would appear to restrict the provider’s ability to comply with the privacy regulation’s requirements. There may, however, be authorities under which either the requirements of the enabling legislation or of the program regulations would impose requirements that differ from these rules.

For example, regulations applicable to the substance abuse block grant program funded under section 1943(b) of the Public Health Service Act require compliance with 42 CFR part 2, and, thus, raise the issues identified above in the substance abuse confidentiality regulations discussion. There are a number of federal programs that, either by statute or by regulation, restrict the disclosure of patient information to, with minor exceptions, disclosures “required by law.” See, for example, the program of projects for prevention and control of sexually transmitted diseases funded under section 318(e)(5) of the Public Health Service Act (42 CFR 51b.404); the regulations implementing the community health center program funded under section 330 of the Public Health Service Act (42 CFR 51c.110); the regulations implementing the program of grants for family planning services under title X of the Public Health Service Act (42 CFR 59.15); the regulations implementing the program of grants for black lung clinics funded under 30 U.S.C. 437(a) (42 CFR 55a.104); the regulations implementing the program of maternal and child health projects funded under section 501 of the Act (42 CFR 51a.6); the regulations implementing the program of medical examinations of coal miners (42 CFR 37.80(a)). These legal requirements would restrict the grantees or other entities providing services under the programs involved from making many of the disclosures that §§ 164.510 or 164.512 would permit. In some cases, permissive disclosures for treatment, payment, or health care operations would also be limited. Because §§ 164.510 and 164.512 are merely permissive, there would not be a conflict between the program requirements, because it would be possible to comply with both. However, entities subject to both sets of requirements would not have the total range of discretion that they would have if they were subject only to this regulation.

Food Drug and Cosmetic Act

The Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq., and its accompanying regulations outline the responsibilities of the Food and Drug Administration with regard to monitoring the safety and effectiveness of drugs and devices. Part of the agency’s responsibility is to obtain reports about adverse events, track medical devices, and engage in other types of post marketing surveillance. Because many of these reports contain protected health information, the information within them may come within the purview of the Privacy Regulations. Although some of these reports are required by the Food, Drug and Cosmetic Act, or its accompanying regulations, other types of reporting are voluntary. We believe that these reports, while not mandated, play a critical role in ensuring that individuals receive safe and effective drugs and devices.

Therefore, in § 164.512(b)(1)(iii), we have provided that covered entities may disclose protected health information to a person subject to the jurisdiction of the Food and Drug Administration for specified purposes, such as reporting adverse events, tracking medical devices, or engaging in other post marketing surveillance. We describe the scope and conditions of such disclosures in more detail in § 164.512(b).

Clinical Laboratory Improvement Amendments

CLIA, 42 U.S.C. 263a, and the accompanying regulations, 42 CFR part 493, require clinical laboratories to comply with standards regarding the testing of human specimens. This law requires clinical laboratories to disclose test results or reports only to authorized persons, as defined by state law. If a state does not define the term, the federal law defines it as the person who orders the test.

We realize that the person ordering the test is most likely a health care provider and not the individual who is the subject of the protected health information included within the result or report. Under this requirement, therefore, a clinical laboratory may be prohibited by law from providing the individual who is the subject of the test result or report with access to this information.

Although we believe individuals should be able to have access to their individually identifiable health information, we recognize that in the specific area of clinical laboratory testing and reporting, the Health Care Financing Administration, through regulation, has provided that access may be more limited. To accommodate this requirement, we have provided at § 164.524(1)(iii) that covered entities maintaining protected health information that is subject to the CLIA requirements do not have to provide individuals with a right of access to or a right to inspect and obtain a copy of this information if the disclosure of the information to the individual would be prohibited by CLIA.

Not all clinical laboratories, however, will be exempted from providing individuals with these rights. If a clinical laboratory operates in a state in which the term “authorized person” is defined to include the individual, the clinical laboratory would have to provide the individual with these rights. Similarly, if the individual was the person who ordered the test and an authorized person included such a person, the laboratory would be required to provide the individual with these rights.

Additionally, CLIA regulations exempt the components or functions of “research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients” from the CLIA regulatory scheme. 42 CFR 493.3(a)(2). If subject to the access requirements of this regulation, such entities would be forced to meet the requirements of CLIA from which they are currently exempt. To eliminate this additional regulatory burden, we have also excluded covered entities that are exempt from CLIA under that rule from the access requirement of this regulation.

Although we are concerned about the lack of immediate access by the individual, we believe that, in most cases, individuals who receive clinical tests will be able to receive their test results or reports through the health care provider who ordered the test for them. The provider will receive the information from the clinical laboratory. Assuming that the provider is a covered entity, the individual will have the right of access and right to inspect and copy this protected health information through his or her provider.

Other Mandatory Federal or State Laws

Many federal laws require covered entities to provide specific information to specific entities in specific circumstances. If a federal law requires a covered entity to disclose a specific type of information, the covered entity would not need an authorization under § 164.508 to make the disclosure because the final rule permits covered entities to make disclosures that are required by law under § 164.512(a). Other laws, such as the Social Security Act (including its Medicare and Medicaid provisions), the Family and Medical Leave Act, the Public Health Service Act, Department of Transportation regulations, the Environmental Protection Act and its accompanying regulations, the National Labor Relations Act, the Federal Aviation Administration, and the Federal Highway Administration rules, may also contain provisions that require covered entities or others to use or disclose protected health information for specific purposes.

When a covered entity is faced with a question as to whether the privacy regulation would prohibit the disclosure of protected health information that it seeks to disclose pursuant to a federal law, the covered entity should determine if the disclosure is required by that law. In other words, it must determine if the disclosure is mandatory rather than merely permissible. If it is mandatory, a covered entity may disclose the protected health information pursuant to § 164.512(a), which permits covered entities to disclose protected health information without an authorization when the disclosure is required by law. If the disclosure is not required (but only permitted) by the federal law, the covered entity must determine if the disclosure comes within one of the other permissible disclosures. If the disclosure does not come within one of the provisions for permissible disclosures, the covered entity must obtain an authorization from the individual who is the subject of the information or de-identify the information before disclosing it. If another federal law prohibits a covered entity from using or disclosing information that is also protected health information, but the privacy regulation permits the use or disclosure, a covered entity will need to comply with the other federal law and not use or disclose the information.

Federal Disability Nondiscrimination Laws

The federal laws barring discrimination on the basis of disability protect the confidentiality of certain medical information. The information protected by these laws falls within the larger definition of “health information” under this privacy regulation. The two primary disability nondiscrimination laws are the Americans with Disabilities Act (ADA), 42 U.S.C. 12101 et seq., and the Rehabilitation Act of 1973, as amended, 29 U.S.C. 701 et seq., although other laws barring discrimination on the basis of disability (such as the nondiscrimination provisions of the Workforce Investment Act of 1988, 29 U.S.C. 2938) may also apply. Federal disability nondiscrimination laws cover two general categories of entities relevant to this discussion: employers and entities that receive federal financial assistance.

Employers are not covered entities under the privacy regulation. Many employers, however, are subject to the federal disability nondiscrimination laws and, therefore, must protect the confidentiality of all medical information concerning their applicants and employees.

The employment provisions of the ADA, 42 U.S.C. 12111 et seq., expressly cover employers of 15 or more employees, employment agencies, labor organizations, and joint labor-management committees. Since 1992, employment discrimination complaints arising under sections 501, 503, and 504 of the Rehabilitation Act also have been subject to the ADA's employment nondiscrimination standards. See "Rehabilitation Act Amendments," Pub. L. No. 102-569, 106 Stat. 4344. Employers subject to ADA nondiscrimination standards have confidentiality obligations regarding applicant and employee medical information. Employers must treat such medical information, including medical information from voluntary health or wellness programs and any medical information that is voluntarily disclosed as a confidential medical record, subject to limited exceptions.

Transmission of health information by an employer to a covered entity, such as a group health plan, is governed by the ADA confidentiality restrictions. The ADA, however, has been interpreted to permit an employer to use medical information for insurance purposes. See 29 CFR 1630 App. at § 1630.14(b) (describing such use with reference to 29 CFR 1630.16(f), which in turn explains that the ADA regulation "is not intended to disrupt the current regulatory structure for self-insured employers ... or current industry practices in sales, underwriting, pricing, administrative and other services, claims and similar insurance related activities based on classification of risks as regulated by the states"). See also, "Enforcement Guidance on Disability-Related Inquiries and Medical Examinations of Employees under the Americans with Disabilities Act," 4, n.10 (July 26, 2000), __ FEP Manual (BNA) __ ("Enforcement Guidance on Employees"). See generally, "ADA Enforcement Guidance on Preemployment Disability-Related Questions and Medical Examinations" (October 10, 1995), 8 FEP Manual (BNA) 405:7191 (1995) (also available at <http://www.eeoc.gov>). Thus, use of medical information for insurance purposes may include transmission of health information to a covered entity.

If an employer-sponsored group health plan is closely linked to an employer, the group health plan may be subject to ADA confidentiality restrictions, as well as this privacy regulation. See *Carparts Distribution Center, Inc. v. Automotive Wholesaler's Association of New England, Inc.*, 37 F.3d 12 (1st Cir. 1994) (setting forth three bases for ADA Title I jurisdiction over an employer-provided medical reimbursement plan, in a discrimination challenge to the plan's HIV/AIDS cap). Transmission of applicant or employee health information by the employer's management to the group health plan may be permitted under the ADA standards as the use of medical information for insurance purposes. Similarly, disclosure of such medical information by the group health plan, under the limited circumstances permitted by this privacy regulation, may involve use of the information for insurance purposes as broadly described in the ADA discussion above.

Entities that receive federal financial assistance, which may also be covered entities under the privacy regulation, are subject to section 504 of the Rehabilitation Act (29 U.S.C. 794) and its implementing regulations. Each federal agency has promulgated such regulations that apply to entities that receive financial assistance from that agency ("recipients"). These regulations may limit the disclosure of medical information about persons who apply to or participate in a federal financially assisted program or activity.

For example, the Department of Labor's section 504 regulation (found at 29 CFR part 32), consistent with the ADA standards, requires recipients that conduct employment-related programs, including employment training programs, to maintain confidentiality regarding any information about the medical condition or history of applicants to or participants in the program or activity. Such information must be kept separate from other information about the applicant or participant and may be provided to certain specified individuals and entities, but only under certain limited circumstances described in the regulation. See 29 CFR 32.15(d). Apart from those circumstances, the information must be afforded the same confidential treatment as medical records, *id.* Also, recipients of federal financial assistance from the Department of Health and Human Services, such as hospitals, are subject to the ADA's employment nondiscrimination standards. They must, accordingly, maintain confidentiality regarding the medical condition or history of

applicants for employment and employees.

The statutes and implementing regulations under which the federal financial assistance is provided may contain additional provisions regulating collection and disclosure of medical, health, and disability-related information. *See, e.g.*, section 188 of the Workforce Investment Act of 1988 (29 U.S.C. 2938) and 29 CFR 37.3(b). Thus, covered entities that are subject to this privacy regulation, may also be subject to the restrictions in these laws as well.